



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,308	01/10/2001	Howard A. Fields	14114.0349U2	9952

23859 7590 07/17/2003
NEEDLE & ROSENBERG, P.C.
SUITE 1000
999 PEACHTREE STREET
ATLANTA, GA 30309-3915

EXAMINER

LI, BAO Q

ART UNIT PAPER NUMBER

1648

DATE MAILED: 07/17/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,308

Applicant(s)

FIELDS ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-25 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-6,9-25 and 32-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on 02/19, 2002 has been entered. Claims 7-8 and 26-31 have been canceled. New claims 32-40 have been entered. Claims 1-6, 9-25 and 32-40 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6 and 23, drawn to an isolated peptide of HCV, classified in class 424, subclass 189.1.

Upon election of Group I, Applicant is additionally required to a single sequence selected from SEQ ID NO: 1-5 to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.

II. Claims 9-22, 24-25, and 40, drawn to a mosaic polypeptide and a method for using the same comprising an isolated antigen epitope selected from different HCV protein, classified in class 424, subclass 228.1.

Upon election of Group II, Applicant is additionally required to a single HCV protein selected from (1) amino acid residues 1-91 of core, (2) NS3, (3) amino acid residues 1789-1867 of NS4, (4) amino acid residues 1916-1948 of NS4, and (5) amino acid residue 2322-2423 of NS5a and its corresponding sequence with SEQ ID NO to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.

III. Claims 32-33 and 24-25, drawn to a mosaic polypeptide comprising two antigenic epitopes, classified in class 424, subclass 192.1.

Upon election of Group III, Applicant is additionally required to two HCV proteins selected from (1) amino acid residues 1-91 of core, (2) NS3, (3) amino acid residues 1789-1867 of NS4, (4) amino acid residues 1916-1948 of NS4, and (5) amino acid

Art Unit: 1648

residue 2322-2423 of NS5a and its corresponding sequences with SEQ ID NOs to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.

IV. Claims 34-35, 24-25, drawn to a mosaic polypeptide comprising three antigenic epitopes, classified in class 424, subclass 185.1.

Upon election of Group IV, Applicant is additionally required to three HCV proteins selected from (1) amino acid residues 1-91 of core, (2) NS3, (3) amino acid residues 1789-1867 of NS4, (4) amino acid residues 1916-1948 of NS4, and (5) amino acid residue 2322-2423 of NS5a and its corresponding sequences with SEQ ID NOs to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.

V. Claims 36-37, 24-25, drawn to a somaic polypeptide comprising four epitopes selected from different HCV proteins, classified in class 424, subclass 202.

Upon election of Group V, Applicant is additionally required to four HCV proteins selected from (1) amino acid residues 1-91 of core, (2) NS3, (3) amino acid residues 1789-1867 of NS4, (4) amino acid residues 1916-1948 of NS4, and (5) amino acid residue 2322-2423 of NS5a and its corresponding sequences with SEQ ID NOs to be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.

VI. Claims 38-39, drawn to a somaic polypeptide comprising an isolated epitope of HCV selected from different HCV protein and additional epitope of HCV core

Art Unit: 1648

protein, wherein the polypeptide is not HCV polypeptide, classified in class 424, subclass 186.1.

Upon election of Group VI, Applicant is additionally required to one HCV protein selected from (1) amino acid residues 1-91 of core, (2) NS3, (3) amino acid residues 1789-1867 of NS4, (4) amino acid residues 1916-1948 of NS4, and (5) amino acid residue 2322-2423 of NS5a and its corresponding sequences with SEQ ID NO be examined on the merits. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitute an independent and patentably distinct invention.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of groups I-VI are directed to different polypeptide, e.g. the polypeptide is a HCV polypeptide only comprising one single HCV protein, whereas the mosaic polypeptide of Group VI is not a HCV polypeptide comprising one or more HCV epitopes derived from an HCV proteins.
3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group VI, restriction for examination purposes as indicated is proper.
4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1648

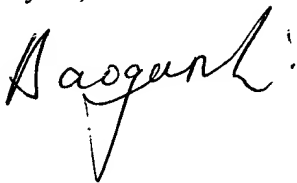
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

July 16, 2003

A handwritten signature in cursive script, appearing to read 'Bao Qun Li', with a large, stylized initial 'B' and a long, sweeping underline.